

## EXHIBIT 13



## Controlled Substance Dispensing Guideline

### PURPOSE:

To provide guidelines for the proper dispensing of controlled substances that support the “corresponding responsibility” mandate placed upon pharmacists to exercise due diligence in the decision to fill or not to fill a controlled substance prescription.

### DISCUSSION: “Corresponding Responsibility”

The United States Controlled Substances Act (CSA) is the statutory basis for federal oversight of controlled substance regulation in the United States. The CSA defines the pharmacist’s affirmative obligation to ensure that controlled substance prescriptions are valid. Under the CSA, a “valid prescription” must be issued for a legitimate medical purpose by an authorized prescriber acting in the usual course of his/her professional practice.

While the responsibility for the proper prescribing is upon the prescriber, a “corresponding responsibility” rests with the pharmacist who dispenses the prescription. In other words, the pharmacist cannot fulfill his/her legal obligations solely by accurately selecting the proper pharmaceutical product, accurately labeling that product for use by the patient and counseling the patient. The pharmacist must exercise sound professional judgment regarding the validity of a prescription prior to dispensing. The pharmacist should not assume that every controlled substance prescription is improper, but rather take appropriate action to ensure the prescription’s validity.

### ENSURE THE VALIDITY OF CONTROLLED SUBSTANCE PRESCRIPTIONS:

1. The pharmacy shall only accept and dispense prescriptions written/ordered by state-authorized practitioners.
  - a. The pharmacist must know and adhere to the laws of each state where he/she practices governing the prescriptive authority of each practitioner.
2. If presented with a questionable prescription, the pharmacist shall verify the legitimacy of such prescription prior to dispensing by contacting the prescriber using an independent source of material (other than the hardcopy prescription) including but not limited to:
  - a. Phone book
  - b. Internet site
  - c. Operator-assisted information
  - d. Pharmacy dispensing system
3. Verify the prescription is written in the usual course of prescriber’s professional scope of practice. For example, dentists are restricted to treatments related to oral health.



4. The pharmacist must have reasonable assurance that a valid prescriber-patient relationship exists.
  - a. A pharmacist may use his/her experience with the patient and/or medical provider(s).
  - b. If the pharmacist questions the validity of the prescriber-patient relationship, the pharmacist shall contact the prescriber to request the following:
    - i. When was the last time the patient saw the prescriber
    - ii. What was the nature of the visit
5. Verify the prescriber DEA registration
  - a. The pharmacist must know the federal and state requirements for the state where he/she practices for prescribers who practice in hospital settings
  - b. The pharmacist must know the federal and state requirements for DEA registration for advance practice nurses, residents, and physician's assistants
  - c. Use the mathematical formula to validate the prescriber's DEA registration
  - d. Compare the prescriber DEA number listed on the prescription to the DEA number retrieved from the pharmacy dispensing system
6. If available, access information related to the prescriber or patient utilizing the state prescription drug monitoring program (PDMP) database. The Pharmacist must have cause before accessing the PDMP. Refer to your state specific PDMP guidelines.
7. In addition to the foregoing, you should review the prescription for any signs of changes, forgery, or alteration
  - a. Consider whether the prescription appears to be photocopied that might indicate duplication of an original order
  - b. Prescriptions pre or post-dated may require further investigation
  - c. Review the quantity and strength for changes; large quantities require a diagnosis or treatment plans from the prescriber
  - d. Ensure the prescriber's original hand-written signature appears on all CII prescriptions
8. Review name, strength, quantity and dosing. Contact the prescriber with questions, and do not always assume excessive doses are forged prescriptions;

#### **APPROPRIATENESS OF CONTROLLED SUBSTANCE PRESCRIPTIONS (Red Flags)**

In addition to ensuring the validity of controlled substance prescriptions, the DEA, in a written opinion suspending a licensed pharmacy for failure to exercise the appropriate follow-up with regards to the dispensing of controlled substances, identified 10 Red Flags that must be considered as part of the due diligence by the pharmacist in evaluating whether to fill a prescription.

1. Prescriptions written together for: oxycodone/hydrocodone (opiate) + alprazolam (benzodiazepine) + carisoprodol (muscle relaxant as a potentiator).
2. Lack of individualization of dosing. [Best practice: individualized according to the patient need using the lowest possible beneficial dose.]
3. Multiple prescriptions for the strongest formulations of hydrocodone and alprazolam.



4. Requests for early dispensing of refills.
5. Further than expected distances of the patient and/or medical provider from the pharmacy.
6. Overwhelming percentage of the pharmacy business devoted to filling controlled substances.
7. Failure to contact and/or follow-up with other pharmacists who are not filling prescriptions from the particular provider in question.
8. Filling prescriptions for patients who arrive in groups.
9. Cash transactions on controls.
10. Verification that a prescription is legitimate is not satisfied simply because the provider performed blood tests and MRI's on the patient.

#### OTHER RED FLAGS THAT SHOULD BE CONSIDERED INCLUDE:

1. Patient has multiple prescriptions but only wants the controls filled.
2. Prescriptions presented late at night or on weekends when the prescriber is unlikely to be available for follow-up calls.
3. Large quantity of medication on a prescription from an emergency room.
4. Younger patients with no history of treatment.
5. Patients requesting a medication by "street name" or insisting on brand.
6. Patients using multiple providers for the same medications.
7. Therapy that does not match the condition.

#### DOCUMENTATION

The pharmacist must document the steps they have taken to verify questionable prescriptions, including any calls to the prescriber, conversations with the patient, medication history review, and notate on the prescription itself or in the computer system utilizing appropriate note fields. This documentation must include:

- Name (first and last) of the individual to whom you spoke
- Date and Time of the conversation
- The phone number used to call the provider
- Brief summary of the substantive conversation

When accessing a PDMP note the date and reason for accessing the database.



## GIANT EAGLE'S PROMISE OF SUPPORT

Giant Eagle supports the professional judgment of each Pharmacy Team Member. If after performing required due diligence and in the exercise of his/her professional judgment, a pharmacist determines that a prescription should not be filled; Giant Eagle will support the decision. No Team Member may try to coerce a Giant Eagle pharmacist to fill a prescription that in his/her professional judgment and after appropriate investigation should not be filled. Any coercion will be considered an ethics violation and will be reported and disciplined according to the Giant Eagle Code of Ethics.